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10/554,062

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MAGERL1

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EXAMINER

MERENE, JAN CHRISTOP L

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/554,062	<b>Applicant(s)</b> MAGERL ET AL.	
	<b>Examiner</b> JAN CHRISTOPHER MERENE	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 1-4, 6-8, 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski US 6,336,927 in view of Huebner et al US 7,090,676.

Regarding **Claim 1**, Rogozinski discloses a device for spondylodesis and in particular for anterior intersomatic spondylodesis of the cervical spine, with at least one intervertebral implant (#220 or #240), that functions as a pressure-absorbing spacer which stabilizes the spondylodesis and ensures that a solid osseous bridge is formed between the adjacent vertebral bodies and with at least one plate (link #220) which is to be connected to the intervertebral implant and to an adjacent vertebra, wherein the intervertebral implant is connected to at least two plates (links #220 and #240) which are arranged at a distance from one another, one end of each of the two plates forming a fixable joint together with the intervertebral implant (see Col 5 lines 8-19, where constructs #210 and #230 form a plurality of links #220 and #240, with securing means in the form of screws, bolts or hook members, as seen in Fig 5 and the examiner notes that with regards to the shape of the plates, Rogozinski discloses various embodiments of the device with various shapes in Figs 1-8B, 10A-11, all of which would have been obvious to use as a way of treating spinal conditions, see abstract).

With regard to the statement of intended use and other functional statements, "pressure absorber," they do not impose any structural limitations on the claims distinguishable over Rogozinski, which is capable of being used as claimed if one so desires to do so. The links of Rogozinski are placed along the spinal column as seen as Fig. 5 and would act absorb pressure and forms a osseous- bridge between adjacent

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vertebra (see col 5 lines 20-21, where the surface of #220 can be used for grafts). *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

However, Rogozinski does not specifically disclose wherein at least one plate has, at least at one end, a hemispherical joint part formed as a unit protruding transversely from said at least one plate, and wherein said joint part has a passage for locking screw and engages in a hemispherical depression of an intervertebral implant to form a ball joint, wherein at least two plates are each connected to an intervertebral implant via a polyaxial joint, in particular a ball joint.

However, Huebner et al US 7,090,676 discloses at least one plate (#84) with a hemispherical joint part formed as a unit wherein said joint part has a passage for locking screw and engages in a hemispherical depression (#128 as seen in Figs 5-6 and see Col 8 lines 40-50, where ball joints allows the plates to be pivoted).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify at least one of the plates of Rogozinski to include the ball joint with the hemispherical depression of Huebner et al (as discussed above), wherein at least two plates are each connected to an intervertebral implant via a polyaxial joint, in particular a ball joint, because a ball joint allows it allows for pivotal movements of the plate (see Col 7 lines 40-50), thereby making the plate pivotably adjustable relative to the member it is being connected to.

Regarding **Claim 2**, Rogozinski teaches a device, wherein at least one of the plates has a Z-shaped, I-shaped or L-shaped configuration (see Fig 5, link #240 as being I-shaped).

Regarding **Claim 3**, Rogozinski teaches a device, where one plate, in a central area extending transversely with respect to the longitudinal axis of the spinal column, has at least one passage for a bone screw, so that this plate can be connected to a vertebra (see Col 5 lines 8-19, where constructs #210 and #230 form a plurality of links #220 and #240, with securing means in the form of screws, bolts or hook members, as seen in Fig 5).

Regarding **Claim 4**, Rogozinski teaches a device, wherein said area has two passages (#222) arranged at a distance from one another and each intended for a bone screw (see Col 5 lines 8-19, where securing means in the form of screws, bolts or hook members, as seen in Fig 5.)

Regarding **Claim 7**, Rogozinski teaches a device, wherein at least two L-shaped plates are connected to an intervertebral implant (see Fig 4, where L-shaped implants, links #10 are connected together).

Regarding **Claim 8**, Rogozinski teaches a device, wherein the two plates (link #10) each having, in extending transversely with respect to the longitudinal direction of the spinal column (ends #12 and #14), at least two passages (apertures #18) which are arranged at a distance from one another and each receive a bone screw (see Col 4 lines 28-31 and Fig 1a, link #10, with apertures #18 on ends #12 and #14, configured to receive a bone screw).

Regarding **Claim 12**, Rogozinski discloses the device, wherein it is provided for spondylodesis of the cervical spine (see Col 1 lines 16-23, wherein the invention relates generally to apparatus and methods for treating and correcting spinal abnormalities or conditions, stabilizing the position of the spine and vertebrae thereof).

5. **Claims 9 and 10** are rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 and Huebner et al US 7,090,676 in further view of Zucherman et al 5,836,948.

Rogozinski and Huebner et al discloses the claimed invention of intervertebral implants (links #10) connected to each other, thus forming Z-shaped plates (refer to Fig 4, wherein links #10 form a Z-shaped plate connect to other L-shaped plates) and all the connections between the plates and the intervertebral implants being designed as polyaxial joints, in particular ball joints (see Col 8 lines 40-50 in Heubner et al).

However Rogozinski and Heubner et al does not does not appear to explicitly disclose a Z-shaped plated.

However, Zucherman et al discloses an intervertebral implant that is Z-shaped (see Figs 69-71).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the links of Rogozinski to be z-shaped because being Z-shaped plates allow for implant to be placed between the two spinous processes (lines Col 15 lines 5-13 in Zucherman), the spinous process projects outwardly, thus a z-shaped plate implant would accommodate the natural anatomy of the spine. Therefore, it would have been obvious to combine Rogozinski and Huebner et al with Zucherman to obtain the invention in the instant claims.

6. **Claim 11** is rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 Huebner et al US 7,090,676 in further view of Lawson 6,074,423.

Rogozinski and Huebner discloses the claimed invention as stated above but does not appear to explicitly disclose at least one plate and/or an intervertebral implant is/are made of a material transparent to X- rays.

However, Lawson discloses an intervertebral implant that made of a material transparent to X- rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having to modify the implant of Rogozinski to include the transparent x-ray

material as taught Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

7. **Claims 13-14, 16** is are rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 and Huebner et al US 7,090,676 and Zucherman et al 5,836,948 as applied to claims 1, 9-10 above in further view of Karpf US 5,000,166.

Regarding Rogozinski, Heubner et al, and Zucherman et al disclose the claimed invention as recited above in claims 1, 9-10 above but does not specifically disclose a kit with a plurality of bone screws and locking screws.

However, Karpf discloses a kit with a similar device with plates and screws (as seen in Figs 1-4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a kit as disclosed above with a plurality of elements as disclosed above because it can accommodate different patients (see Col 2 lines 26-30). It would also have been obvious to provide a kit because of the numerous plates and screws employed in Rogozinski (see Figs 4-5, 7)

8. **Claim 15** is rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 and Huebner et al US 7,090,676 and Zucherman et al 5,836,948, and Karpf US 5,000,166 as applied to claim 13 above in further view of Lawson 6,074,423.

Rogozinski, Huebner et al, Zucherman et al and Karpf discloses the claimed invention as stated above but does not appear to explicitly disclose at least one plate and/or an intervertebral implant is/are made of a material transparent to X- rays.

However, Lawson discloses an intervertebral implant that made of a material transparent to X- rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having to modify the kit of Rogozinski, Huebner et al, Zucherman et al and Karpf to include the transparent x-ray material as taught by Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

9. **Claim 17** is rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927, Huebner et al US 7,090,676, Zucherman et al 5,836,948, Karpf 5,000,166 as applied to claims 13-16 above, in further view of Mast 5,269,784.

Rogozinski, Huebner et al, Zucherman et al and Karpf disclose the claimed invention as recited above but does not explicitly disclose locking screws that are ball-head screws having a screw head, which are substantially hemispherical on its underside.

However, Mast teaches locking screws that are ball-head screws having a screw head, which is substantially hemispherical on its underside (screw #15).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the locking screw (#150) of Rogozinski to be hemispherical on the underside as taught by Mast because it has universal applicability since it can be used together with any type of bone plates and screws and may be used selectively at single positions of the bone plate, respectively with single bone screws inserted therein (see Col 3 lines 9-16). The hemispherical underside also helps to accommodate the screw to the hemispherical depression of the ball joint as taught by Heubner et al.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection (see above).

11. The examiner's objection to the drawings has been overcome.

### ***Conclusion***

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone

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number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCM

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Examiner, Art Unit 3733

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